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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,804	08/17/2006	Takeo Ishiyama	0020-5505PUS1	2397

2292 7590 12/11/2008  
BIRCH STEWART KOLASCH & BIRCH  
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FALLS CHURCH, VA 22040-0747

EXAMINER
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ZAREK, PAUL E

ART UNIT	PAPER NUMBER
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1617

NOTIFICATION DATE	DELIVERY MODE
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12/11/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/589,804	<b>Applicant(s)</b> ISHIYAMA, TAKEO	
	<b>Examiner</b> Paul Zarek	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16-20 and 22 is/are pending in the application.
- 4a) Of the above claim(s) 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/17/2006, 08/30/2007, 06/19/2008</u> .                      | 6) <input type="checkbox"/> Other: _____                          |



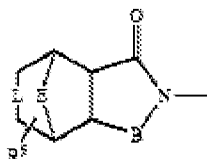
## DETAILED ACTION

### *Status of the Claims*

1. Claims 1-15 and 21 have been cancelled, Claims 16-20 were amended and Claim 22 was added by the Applicant in correspondence filed on 10/23/2008. Claims 16-20 and 22 are currently pending. This is the first Office Action on the merits of the claim(s).

### *Election/Restrictions*

2. Applicant's election with traverse of Group III, drawn to a compound of formula I wherein Z is



in the reply filed on 10/28/2008 is acknowledged. The traversal is on the ground(s) that Examiner should examine all species of formula I should the elected species of Z be found allowable. This is not found persuasive because the embodiments of Z, restricted in Groups III-VII, render the resultant compounds non-obvious variants of each other, thereby representing non-overlapping subject matter.

The requirement is still deemed proper and is therefore made FINAL.

3. Acknowledgement is also made of the species election of lurasidone (also known as SM-13496). Claims 16-20 read on the elected species.

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4. Newly submitted Claim 22 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 22 is drawn to a method of treating memory/learning dysfunction caused by schizophrenia, whereas Group III was restricted to a specific genus of compounds. Had Claim 22 been a part of the initial set of claims, it would have been restricted to its own group.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, Claim 22 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

#### ***Priority***

5. Applicant's claim for the benefit of a prior-filed international application, PCT/JP05/02838 (filed on 02/16/2005) under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. The effective filing date of the instant application is 02/16/2005.

6. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) to Japanese application 2004-044986 (filed on 02/20/2004). The foreign priority date of the instant application is 02/20/2004.

#### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 16-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Saji, et al. (US Patent No. 5,532,372, 1996).

9. Claim 16 of the instant application is drawn to a therapeutic agent for memory/learning dysfunctions caused by schizophrenia comprising formula I or an acid salt thereof, of which lurasidone is the elected species. Claims 17-19 limit the various substituents of formula I. Claim 20 limits the compound to lurasidone.

10. Saji, et al., specifically teach lurasidone or an acid salt thereof (Claim 14). Saji, et al., further disclose that the compounds disclosed in the patent can be used as anti-psychotic agents, "especially for therapy of schizophrenia" (abstract). Therefore, Saji, et al., anticipate all the limitations of the rejected claims.

### ***Conclusion***

11. No claims are allowed

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/SREENI PADMANABHAN/  
Supervisory Patent Examiner, Art Unit 1617